

Remarks

Applicants gratefully acknowledge the previous allowance of claims 10-12, 46-48 and 52-53.

Amendments to the Claims

Entry of the above amendments and reconsideration and withdrawal of the rejection of claims 40-43 and 50-51 is respectfully requested. Claims 1-5 and 44-45 have been canceled by this amendment. Claims 40-41 have been amended by making those claims depend from claim 10 rather than from claim 1, and by deletion of the term "an optical or geometric isomer thereof;" from those claims. Support for these amendments is in the specification and in the claims, particularly claim 10, as originally filed. Claim 43 has been amended by making it depend from claim 10 rather than from claim 1. Support for this amendment is in the specification and in the claims, particularly claim 10, as originally filed. Claim 46 has been amended by deletion of the term "an optical or geometric isomer thereof;" from that claim. Claim 50 has been amended by making it depend from claims 46, 47 or 48 rather than claim 45, specifying that (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-5,6,7,8-tetrahydro-naphthalene-2-ol, D-tartrate is administered and by deletion of the term "wherein the female subject is postmenopausal." Support for this amendment is in the specification and claims as originally filed. Claim 51 has been amended by making it depend from claim 48 rather than claim 45. New claims 54 and 55 have been added. Applicants respectfully submit that support for these amendments is in the specification as originally filed and no new matter was introduced by these amendments. Multiple dependent claim fee is being paid for claim 50 which is multiply dependent (dependent on claims 46-48). If any additional fees are required for the amendments to the claims please charge those fees to deposit account 16-1445.

35 U.S.C. § 102(e) Rejection of Claims 1, 2 and 40

Claims 1, 2 and 40 have been rejected under 35 U.S.C. 102(e) as allegedly being unpatentable over Place et al. (U.S. Patent 5,877,216 issued March 2, 1999, hereinafter referred to as "Place"). The Examiner has alleged that Place teaches a composition for treating sexual dysfunction and that estrogen antagonists such as tamoxifen, raloxifene and centchroman are disclosed. Applicants respectfully

request the Examiner reconsider this rejection in view of the amendments to the claims.

Claims 1-2 have been canceled thereby rendering the instant rejection of those claims moot. Applicants presently claim a method of treating sexual arousal disorder using an estrogen agonist/antagonist, and a cyclic guanosine 3', 5'-monophosphate elevator. Claim 40, as amended, now depends from previously allowed claim 10 and thereby recites the term "consisting of" immediately after the preamble of the claim. The "consisting of" language, when used immediately after the preamble of the claim, excludes any element, step or ingredient not specified in the claim (see *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) and MPEP 2111.03. Thus, the present amendment to claim 40 limits it to the specific steps and to the administration of the specific compositions described in those steps.

Place does not teach or disclose the presently claimed method of treating sexual arousal disorder using an estrogen agonist/antagonist, and optionally, a cyclic guanosine 3', 5'-monophosphate elevator and therefore does not anticipate claim 40 as amended.

Place does not supply each of the elements of the presently claimed invention. Place discloses the local administration of vasodilating agents to the vagina or vulva. While Place discloses combinations of estrogen agonist/antagonists, Place does not disclose the instant combination of an estrogen agonist/antagonist and a cyclic guanosine 3', 5'-monophosphate elevator as in claim 40. Since Place does not disclose the present method of treating sexual arousal disorder by administration of an estrogen agonist/antagonist along with a cyclic guanosine 3', 5' monophosphate elevator, it thus does not anticipate the instant method of claim 40. For this reason applicants respectfully request that the Examiner reconsider and withdraw the 35 U.S.C. § 102(e) rejection of claim 40, as amended.

35 U.S.C. § 103(a) Rejection of Claim 2-4 and 40-44; and Claims 5, 45 and 50-51

Claims 3-4 and 41-44 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable as obvious over Place. Applicants respectfully request the Examiner reconsider this rejection in view of the amendment to the claims. Claims 3-4 and 44 have been canceled by this amendment, thereby rendering the

instant rejection of those claims moot. Place does not teach or suggest the presently claimed method of treating sexual arousal disorder using an estrogen agonist/antagonist and a cyclic guanosine 3', 5'-monophosphate elevator as in instant claims 41-43.

Place does not supply the elements of the instant claims 41-43, nor does it suggest the presently claimed method. Place is concerned with the local administration of vasodilating agents to the vagina or vulva. Place does not mention or suggest the particular estrogen agonists/antagonists that are recited in claims 41-43. Also, there is no motivation in Place to arrive at the present method of claims 41-43. Place is concerned only with the local administration of compounds to the vagina or vulva and never mentions administration of an estrogen agonist/antagonist together with a cyclic guanosine 3',5'-monophosphate elevator. Thus, there can be no suggestion in Place to use an estrogen agonist/antagonist in combination with an cyclic guanosine 3',5'-monophosphate elevator to treat sexual arousal disorder in females.

Applicants respectfully submit that Place does not teach or suggest that an estrogen agonist/antagonist in combination with a cyclic guanosine 3', 5' monophosphate elevator could be used to treat sexual arousal disorder in females. Applicants respectfully request the Examiner to reconsider and withdraw the 35 U.S.C. rejection of claims 41-43, as amended.

Claims 5, 45 and 50-51 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable as obvious over Place in view of Chiu et al. Claims 5 and 45 have been canceled, thereby rendering the instant rejection moot with respect to those claims. Claims 50-51 have been amended as described above.

Chiu et al discloses the tartrate salt of (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-5,6,7,8-tetrahydro-naphthalene-2-ol. Place does not disclose or suggest the use of an estrogen agonist/antagonist in combination with a cyclic guanosine 3', 5' monophosphate elevator to treat sexual arousal disorder in females as discussed above. Combination of Chiu and Place does not result in nor does it suggest the instantly claimed method. Place teaches the use of certain vasodilators, potentially in combination with other agents to treat female sexual dysfunction. Incorporating the (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-5,6,7,8-tetrahydro-naphthalene-2-ol as taught by Chiu into the method of Place results in a method where a vasodilator must be administered optionally with the (-)-cis-6-phenyl-

5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-5,6,7,8-tetrahydro-naphthalene-2-ol. This method is not the method as claimed in claims 50-51. Neither Place nor Chiu provide motivation to one of ordinary skill in the art to modify the method of Place to arrive at the method of instant claims and 50-51 since there is simply no suggestion to do so.

Applicants respectfully assert that Place in view of Chiu does not teach or suggest that (-)-cis-6-phenyl-5-[4-(2-pyrrolidin-1-yl-ethoxy)-phenyl]-5,6,7,8-tetrahydro-naphthalene-2-ol, or its D-tartrate salt in combination with a cyclic guanosine 3', 5' monophosphate elevator, could be used to treat sexual arousal disorder in females. Applicants respectfully request the Examiner to reconsider and withdraw the 35 U.S.C. rejection of claims 50-51, as amended.

#### Conclusion

Applicants believe that, in view of the amendments and remarks made above, this application is in condition for allowance. Reconsideration and allowance of claims 40-43 and 50-51 and new claims 54-55 is respectfully requested.

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